

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Tfwj 652

In re Patent Application of

SQUIRRELL et al.

Serial No. 09/763,824

Filed: February 27, 2001

Title: NOVEL ENZYME

Atty Dkt. 1498-119

C# M#

TC/A.U.

1652

Examiner: Steadman, David

Date: April 15, 2005



Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RULE 181 PETITION

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

 Correspondence Address Indication Form Attached.**Fees are attached as calculated below:**

Total effective claims after amendment	0	minus highest number			
previously paid for	20	(at least 20) =	0 x \$50.00	\$0.00 (1202)/\$0.00 (2202)	\$
Independent claims after amendment	0	minus highest number			
previously paid for	3	(at least 3) =	0 x \$200.00	\$0.00 (1201)/\$0.00 (2201)	\$

If proper multiple dependent claims now added for first time, (ignore improper); add
\$360.00 (1051)/\$180.00 (2051) \$

Petition is hereby made to extend the current due date so as to cover the filing date of this
paper and attachment(s)
One Month Extension \$120.00 (1251)/\$60.00 (2251)
Two Month Extensions \$450.00 (1252)/\$225.00 (2252)
Three Month Extensions \$1020.00 (1253)/\$510.00 (2253)
Four Month Extensions \$1590.00 (1254)/\$795.00 (2254) \$

Terminal disclaimer enclosed, add
\$130.00 (1814) / \$65.00 (2814) \$

Applicant claims "small entity" status. Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee
\$180.00 (1806) \$

Assignment Recording Fee
\$40.00 (8021) \$

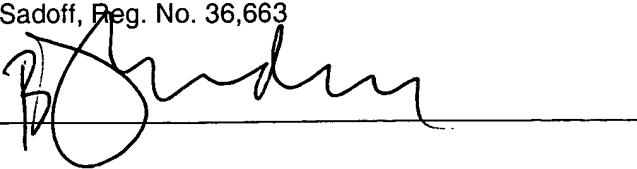
Other:
\$

TOTAL FEE ENCLOSED \$ 0.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: 



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For: NOVEL ENZYME

* * * * *

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The Director is requested to invoke his supervisory authority and review and withdraw the restriction requirement of the Examiner in the above.

The restriction require has been made final in the Office Action of December 15, 2004.

An Amendment filed in response to the Office Action of December 15, 2004 is attached. The applicants request a Decision on the present Petition prior to issuance of a further Office Action by the Examiner as the Decision may alter the scope of examination.

The applicants elected, with traverse, the subject matter of the Examiner's Group I in response to the Office Action dated January 30, 2004, and also elected species Ia, for further prosecution in the above.

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Reconsideration and withdrawal of the restriction requirement are requested for any of the following reasons.

The Director will appreciate that the present application is a 371 U.S. national phase of PCT/GB99/03538. The principles of unity of invention, as opposed to U.S. restriction practice, apply.

The applicants submit, with due respect, that the Examiner has artificially, and without basis in the Rules, attempted to define as "special technical features" of the claimed subject matter, the reference sources of the claimed variants, i.e., *Photinus pyralis* (Group I), *Luciola mingrellica* (Group I), *L. cruciata* (Group III), *L. lateralis* (Group IV), *Hotaria paroula* (Group V), *Pyrophorous plagiophthalmus* (Group VI), *Lampyris noctiluca* (Group VII), *Pyrocoelia nayako* (Group VIII), and *Photinus pennsylvanicus* (Group IX). Within Groups (I) – (IX), the Examiner has asserted that 8 separate inventions are defined within Group I, 8 separate inventions are defined within Group II, 8 separate inventions are defined within Group III, and 8 separate inventions are defined within Group (IV), corresponding to individually disclosed mutations. Further, the Examiner has asserted that plants of claim 26 define 37 separately patentable inventions. (Claim 27, while indicated as pending, is not included in any of the Examiner's Groups. In fact, claim 27 was canceled by way of a Preliminary Amendment filed February 27, 2001.)

The only articulated basis for the Examiner's assertion of lack of unity of invention is reliance of "Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions" and a conclusion that the claimed "polypeptides are not regarded as being of similar nature because all alternatives do not share a common structure." See, page

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9 of the Office Action dated January 30, 2004 (Paper No "01232004", as referred to in the footer of page 1 of the Office Action).

The Examiner provides no technical or scientific support for his conclusion.

Section (f) of Annex B of the PCT Administrative Instructions (hereinafter "Annex B") provides as follows:

(f) "**Markush Practice.**" The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)

(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)

(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be

substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

The Examiner admits that the claimed polypeptides "share a common property or activity." See, page 9 of Paper No. 01232004. The requirement of Section (f)(i)(A) of Annex B is admitted by the Examiner to be met.

The claimed polypeptides, and other aspects of the claimed invention based thereon, share a common structure (i.e., "a significant structural element is shared by all of the alternatives"). Specifically, the Director will appreciate that luciferases, i.e., the proteins of the claimed invention, are highly conserved as a group of proteins.

Moreover, luciferases are obtainable from a limited number of sources. All known luciferases share a very high degree of homology with one another, as is clear from Ye et al., *Biochimica et Biophysica Acta*, 1339 (1997) 39-52 (copy attached), which is referenced on page 1 lines 22 to 24 of the specification. It is clear from Ye et al., and in particular from Figure 2 of the same, that there are many motifs within the luciferase proteins that are common to all known luciferases, indicated by dark shading, as well as many other motifs which contain only conservatively substituted amino acid residues. Therefore the basis for the Examiner's restriction requirement is not well founded and the Examiner's lack of unity conclusion should be withdrawn.

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The applicants note, for completeness, that even the U.S. Patent Office has previously recognized that luciferases from different sources (i.e., the basis for the present Examiner's unity objection) share a common structure. Specifically, the Director is requested to see the claims of the attached U.S. Patent No. 6,132,983, which provides luciferases generally.

The present applicants set out to identify luciferases which have an improved property, i.e., enhanced thermostability, and this was achieved by defining a group of specific amino acid residues within the protein which impact on the thermostability, of these conserved proteins. The particular residues can be precisely identified by their common position in the protein structures. It is believed that this is further evidence of the common structure found amongst this protein group.

As a result, the applicants submit that the restriction requirement is unjustified and the claims define a common special technical feature.

Withdrawal of the restriction requirement in a favourable Decision on this Petition and an Action on the merits of the full breadth of the claimed invention are requested.

No fee is believed to be required for consideration of this Petition as the Petition is believed to only be required due to Patent Office error in the Examiner maintaining the restriction requirement. The Office is authorized however by the attached cover sheet to charge the undersigned's Deposit Account No. 14-1140 for any fee required for consideration of the present Petition.

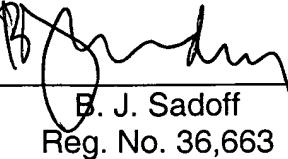
A favorable Decision on the present Petition is requested.

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Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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